DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0041]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Content of Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Content of Labeling.'' This draft guidance is one in a series of guidance documents on providing regulatory submissions to the FDA in electronic format. In the **Federal Register** of December 11, 2003 (68 FR 69009), FDA published a final regulation (the electronic labeling rule) requiring that the content of labeling for marketing applications be submitted in electronic format in a form that FDA can process, review, and archive. The draft guidance provides information on submitting the content of labeling in electronic format for review with new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biological license applications (BLAs).

DATES: Submit written comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD

20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Randy Levin, Center for Drug Evaluation and Research (HFD–140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5411, e-mail: *levinr@cder.fda.gov*, or

Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

In December 2003, FDA published the electronic labeling regulation, which requires the submission of the content of labeling in electronic format for marketing applications. The requirements of the electronic labeling rule can be found in 21 CFR 314.50(l) for NDAs, 21 CFR 314.94(d) for ANDAs, 21 CFR 601.14(b) for BLAs, and 21 CFR 314.81(b) for annual reports on marketing applications. The regulations specify that the content of labeling must be submitted electronically in a form that FDA can process, review, and archive.

The regulations also state that FDA will periodically issue guidance on how to provide the electronic submission.

II. The Draft Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Content of Labeling.'' The draft guidance provides information on how to submit the content of labeling in electronic format.

In the preambles of the proposed and final rules on electronic labeling, FDA identified portable document format (PDF) as the only type of electronic file format that the agency has the ability to accept for processing, reviewing, and archiving. Recent recommendations from the Institute of Medicine and the National Committee on Vital and Health Statistics and mandates in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) have created a new role for electronic labeling information. Electronically formatted content of labeling will be used to support health information management initiatives such as electronic prescribing and the electronic health record (EHR).

Because FDA's current procedures using PDF are not adequate to support these initiatives, the agency is proposing to change the way it processes, reviews, and archives the content of labeling. We are proposing to adopt a new technology for exchanging information between computer systems developed by Health Level Seven (HL7), a standards development organization accredited by the American National Standards Institute. The new technology, Clinical Document Architecture (CDA), allows information to be exchanged in extensible markup language (XML) and is the standard being investigated for the EHR. FDA, working with other interested parties in HL7, has adapted CDA

for labeling in a proposed HL7 standard called Structured Product Labeling (SPL).

FDA is developing an automated system using SPL for processing and managing labeling and labeling changes. When the draft guidance is finalized, absent significant objections, FDA is likely to identify SPL in public docket number 92S–0251 as a format that we can use to process, review, and archive the content of labeling. During our transition to the automated system, the agency would be able to accept the content of labeling in either PDF or SPL file format. After the automated system is implemented, PDF would no longer be a format that we can use to process, review, and archive the content of labeling. At this time, it is our goal to complete the transition to SPL format for content of labeling submissions by the end of 2004.

This draft guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on providing in electronic format the content of labeling required in 21 CFR parts 314 and 601. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received

comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

The information requested for human drug and biological products in this guidance is already covered by the collection of information in ''Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format'' (Office of Management and Budget control number 0910–0530, expiring November 30, 2006).

V. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or at *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: January 25, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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